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09/582,741	10/06/2000	IB Mendel-Hartvig	10806-128	1595

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EXAMINER	
COUNTS, GARY W	
ART UNIT	PAPER NUMBER
1641	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/582,741	Applicant(s) MENDEL-HARTVIG ET AL.	
	Examin r Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 1 "a method in a process" is vague and indefinite. How is "a method" related to "a process" it is unclear what applicant intends.

Claim 1, line 4 "Reactant I" is vague and indefinite. The recitation "I" is confusing, does this mean it is reactant 1 or does "I" symbolize something else? Also

how is "Reactant I" related to "Reactant" are they the same? See deficiencies throughout the claims.

Claim 1, line 4 "Analyte' " is vague and indefinite. It is unclear what " ' " represents. See deficiencies throughout the claims.

Claim 1, line 5 "Reactant*" is vague and indefinite. It is unclear what "*" represents. Also how is "Reactant*" related to "Reactant I"and to "Reactant"

Claim 5, line 2 "have the ability to" is vague. Does the analyte biospecifically bind to the reactant or not?

Claim 5, line 3 the recitation "via" is vague and indefinite. It is unclear what the term encompasses. See deficiencies found throughout the claims.

Claim 5, line 3 "equivalent binding sites" is vague. It is unclear what applicant intends.

Claim 6, line 2 "etc." is vague and indefinite. The recitation does not define the metes and bounds of the claim. See deficiencies throughout the claims.

Claim 8, line 4 "the same process flow" there is insufficient antecedent basis for this limitation. Also the recitation "process flow is vague". It is unclear if the flow is from side to side or top to bottom.

Claim 8, line 5 the recitation "various calibration zones" is vague. The term "various" is subjective and does not encompass the metes and bounds of the claim.

Claim 9, line 5 "the respective process flow" there is insufficient antecedent basis for this limitation.

Claim 10, line 3 "the process flow" there is insufficient antecedent basis for this limitation.

Claim 11, line 12 the recitation "upstream" is vague. Does upstream mean from one side to the other (horizontal) or top to bottom (vertical). It is difficult to understand without any drawings or clear disclosures in the specification. See deficiencies throughout the claims. The same applies to the recitation "downstream" in claim 11.

Claim 11, line 7 "Capturer" is vague and indefinite. It is unclear if the "Capturer" is the same as the binder or if this term encompasses something else. See deficiencies throughout the claims.

Claim 11, line 7 "firmly" is vague. It is unclear what the term encompasses. See also deficiency found in claims 23, 25 and 26.

Claim 11, line 8 the recitation "is able to" is vague. Does the reactant directly or indirectly bind Reactant I or not?

Claim 11, line 10 "may have been" is vague. Was the Reactant* predeposited or not?

Regarding claim 11, line 15, the phrase "preferably" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "preferably"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim 11, part (d) is vague and indefinite. It is unclear how all three steps would be done simultaneously.

Claim 12, line 2 "KZ" is vague. The term is confusing because the calibration zones were previously referred to as CZ.

Claim 14, line 3 "in that" should be deleted for clarification of the language.

Claim 14, line 18 "vice versa" is vague. It is unclear what applicant intends.

Claim 15, line 6 "and" is vague and confusing. It is unclear how (i) and (ii) could be done simultaneously. Consider replacing "and" with or.

Claim 16, line 3 "if there is a detection zone" is vague and indefinite. Is there a detection zone or not?

Claim 17 is vague because it is unclear how both parts (a) and (b) could be done simultaneously. Consider saying (a) or (b).

Claim 17, line 4 "antigen/hapten" is vague. Does this mean that Reactant I is an antigen or a hapten, or does it mean that Reactant is a antigen-hapten complex.

Claim 20, line 8, "this" is vague. Possibly applicant intends --said--.

Claim 20, line 12 "is able to" is vague. Does the "Reactant*" bind to the calibrator binding sites or not?

Claim 21, line 4 the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 24, lines 3 and 4 "where upstream or downstream locations are preferred" is not a positive recitation and therefore renders the claim vague and indefinite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 7, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Robinson et al (WO 95/16914).

Robinson et al disclose a method and device for determining an analyte in a sample involving biospecific affinity reactions. Robinson et al disclose the use of calibration zone(s), in which a calibration reagent is immobilized and has biospecific affinity for the analyte of interest or the binding partner of interest (page 15, lines 15-24). Robinson et al also teach the use of ancillary reagents such as analyte analogues and labeled antibodies. Robinson et al also disclose that the specific binding partner can be coupled to or conjugated to the calibrator (see page 17), to form a complex for detection. Robinson et al disclose that the reagents may be antigen/antibody complexes. Robinson et al disclose that the device may be a flow through device such as a lateral flow matrix (page 5, lines 7-22). Robinson et al disclose the use of measurement zones (detection zones). Robinson et al also disclose that multiple measurement zones may be used to simultaneously or sequentially assay for ligands in the same sample to be conducted (page 7, lines 7-15). Robinson et al disclose that the application zone of the sample is upstream of the detection zone and that the detection zone is upstream of the other zones (figure 4). Robinson et al disclose monitoring the

sample value and comparing the sample value to one or more calibrators which corresponds to a standard amount of analyte. Robinson et al also disclose incubating the sample with one or more ancillary reagents (page 15, lines 19-33).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 8, 9, 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al (WO 95/16914) in view of Davis et al (US Patent 6,352,862).

See above for teachings of Robinson et al.

Robinson et al differ from the instant invention in failing to teach transporting Reactant* through the calibrator zones. Robinson et al also differ from the instant invention in failing to disclose the application zone for the Reactant* is common to the application zone of the sample. Robinson et al also fail to disclose that the Reactant* has particles as analytically detectable group.

Davis et al disclose a lateral flow device which incorporates a labeled specific binding reagent (Reactant*) which is freely mobile when in the moist state. Davis et al disclose that this labeled specific binding reagent is released when liquid sample is applied. Davis et al also disclose that the application of the labeled specific binding reagent in this manner allows for enhanced sensitivity of the test (col 3, lines 7-56). Davis et al also disclose that the labeled specific binding reagent comprises a specific

binding reagent attached to a particulate label such as particles. Davis et al disclose that they can be used to produce an instant analytical result without the need to add further reagents in order to develop a detectable signal and that they are robust and stable and can be used readily in an analytical device which is stored in the dry state.

It would have been obvious to one of ordinary skill in the art to incorporate transportation of the Reactant* as taught by Davis et al into the method of Robinson et al because Davis et al shows that the application of the labeled specific binding reagent in this manner allows for enhanced sensitivity of the test.

It would have also been obvious to of ordinary skill in the art to incorporate the use of particulate labels as taught by Davis et al into the method of Robinson et al because Davis et al that they can be used to produce an instant analytical result without the need to add further reagents in order to develop a detectable signal and that they are robust and stable and can be used readily in an analytical device which is stored in the dry state.

With respect to separate calibrator zones being located in separate process flows as recited in the instant claims. Robinson et al teaches that the different assays may be sequential or simultaneous and therefore, if they are carried out simultaneously they have to be in different process flows.

With respect to the process flow, and the process flows lacking a detection zone and the complex is formed in a detection zone in a process flow lacking a calibrator zone and being present in a matrix of the same type as the calibrator zones as recited in the instant claims the optimum condition for the determination of process flows can be determined by routine

experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al (WO 95/16914) in view of Davis et al (US Patent 6,352,862 as applied to claim 1 above, and further in view of Self et al (US Patent 4,446,231).

See above for teachings of Robinson et al and Davis et al.

Robinson et al and Davis et al differ from the instant invention in failing to teach the diagnosis of an autoimmune disease.

Self et al disclose that immunoassays are used for the detection and/or determination of autoimmune diseases. Self et a disclose shows that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances.

It would have been obvious to one of ordinary skill in the art to use immunoassays as taught by Self et al for the diagnosis of autoimmune diseases because Self et al that immunoassays are used for the detection and/or determination of autoimmune diseases and that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances.

8. Claims 20-25, and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al (WO 95/16914) in view of Davis et al (US Patent 6,352,862).

Robinson et al disclose a device for determining an analyte in a sample involving biospecific affinity reactions. Robinson et al disclose the use of calibration zone(s), in which a calibration reagent (calibrator or binding partner) is immobilized and has biospecific affinity for the analyte of interest or the binding partner of interest (page 15, lines 15-24). Robinson et al also teach the use of ancillary reagents such as analyte analogues and labeled antibodies. Robinson et al also disclose that the specific binding partner can be coupled to or conjugated to the calibrator (see page 17), to form a complex for detection. Robinson et al disclose that the reagents may be antigen/antibody complexes. Robinson et al disclose that the device may be a flow through device such as a lateral flow matrix (page 5, lines 7-22). Robinson et al disclose that the application zone of the sample is upstream of the detection zone and that the detection zone is upstream of the other zones (figure 4). Robinson et al

disclose that the application zone of Reactant* is located downstream of the application zone of the sample (see figure 4).

Robinson et al differ from the instant invention in failing to teach an application zone for Reactant* upstream of calibrator zones.

Davis et al disclose a lateral flow device which incorporates a labeled specific binding reagent (Reactant*) which is freely mobile when in the moist state. Davis et al disclose that this labeled specific binding reagent is released when liquid sample is applied. Davis et al also disclose that the application of the labeled specific binding reagent is upstream of the other zones. Davis et al disclose that by applying the labeled specific binding reagent upstream of the other zones allows for enhanced sensitivity of the test, because a substantial quantity of the liquid sample is able to take up the labeled reagent before migrating through the carrier material to the detection zone (col 3, lines 7-56).

It would have been obvious to one of ordinary skill in the art to incorporate the application of Reactant* as taught by Davis et al into the device of Robinson et al because Davis et al shows that by applying the labeled specific binding reagent upstream of the other zones allows for enhanced sensitivity of the test, because a substantial quantity of the liquid sample is able to take up the labeled reagent before migrating through the carrier material to the detection zone.

9. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al in view of Davis et al as applied to claims 20-25 and 27-31 above, and further in view of Weng et al (US Patent 4,740,468).

See above for teachings of Robinson et al and Davis et al.

Robinson et al and Davis et al differ from the instant invention in failing to teach an immobilized reactant that is biospecific to a second reactant which in turn has biospecific affinity to the analyte.

Weng et al disclose the use of a specific binding partner that is biospecific to a second binding partner, which is in turn specific for the analyte (col 2, lines 47-53). Weng et al disclose that is useful for determining the presence of an analyte in a sample suspected of containing the analyte (col 2, lines 39-41) and also allows for the determination of a plurality of analytes in a test solution (col 3, lines 20-27).

It would have been obvious to one of ordinary skill in the art to incorporate the use of an immobilized specific binding partner (reactant) as taught by Weng et al into the device of Robinson et al because Weng et al shows that this specific binding partner allows for the determination of a plurality of analytes in a test solution

10. Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al in view of Davis et al as applied to claim 20 above, and further in view of Boguslaski et al (US Patent 5,420,016).

See above for teachings of Robinson et al and Davis et al.

Robinson et al and Davis et al differ from the instant invention in failing to disclose packaging the components into a kit.

Boguslaski et al disclose assembling various system components into a test kit. By assembling these components into test kits, it makes it more convenient and facile for the test operator (col 7, lines 8-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to assemble the various components into kits such as taught by Boguslaski et al because Boguslaski shows that test kits make it more convenient and facile for the test operator.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Robinson et al (US Patent 6,027,944) disclose a method in which calibration occurs within the assay, which is achieved by using one or more calibration regions. In at least one of the calibration regions a non-zero signal results, either because of the presence of a calibration reagent or as a result of a binding reaction analogous to that which takes place in the measurement region.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
March 29, 2002

LONG V. LE
SUPERVISORY PATENT EXAMINER
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04/05/02